

In the claims:

1. (Currently Amended) A composition ~~comprising a plurality of active pharmaceutical ingredients~~ consisting of the active pharmaceutical ingredients phenylephrine, pyrilamine, and dextromethorphan, and a liquid pharmaceutical carrier, the composition formed from a method comprising:

(a) ~~forming a solution by dissolving the salt or free base of said active pharmaceutical ingredients in a solvent~~ dissolving the salt or free base of said active pharmaceutical ingredients in a first solvent to form a first solution;

(b) ~~mixing a dispersing agent and tannic acid in a second solvent to form a first dispersion; forming a dispersion by mixing a dispersing agent and tannic acid in a solvent;~~

(c) combining the first solution and the first dispersion under stirring to form a second solution, wherein said second solution comprises the tannate salts of the active pharmaceutical ingredients;

(d) ~~combining substances to form said liquid pharmaceutical carrier, wherein said substances are selected from the group consisting of~~ preservatives, suspending agents, thickening agents, coloring agents, anti-caking agents, sweetening agents, flavoring agents, and pH adjusting agents; and

(e) combining the second solution, without isolation or purification, with said liquid pharmaceutical carrier to produce a liquid dosage form that includes the tannate salts of pyrilamine, phenylephrine and dextromethorphan, at least one suspending agent to produce a homogeneous suspension including pharmaceutically active tannate salts, the homogeneous suspension being homogeneous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units.

2. (Previously Presented) The composition of claim 1 wherein the active pharmaceutical ingredients are present in a range of 0.05% to 25% by weight.

3. (Currently Amended) The composition of claim 1 wherein the salt or free base of said active pharmaceutical ingredients are selected from the group ~~of salts~~ consisting of maleate, citrate, chloride, bromide, acetate, and sulfate, ~~and combinations thereof~~.

4. (Previously Presented) The composition of claim 1 wherein the tannic acid is natural or synthetic.

5. (Currently Amended) The composition of claim 1 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds, ~~and combinations thereof~~.
6. (Previously Presented) The composition of claim 5 wherein the dispersing agent is magnesium aluminum silicate and is present in a range of 0.05% to 5.0% by weight.
7. (Previously Presented) The composition of claim 1 wherein the tannic acid is present in a range of 0.01% to 30.0% by weight.
8. (Previously Presented) The composition of claim 6 wherein the magnesium aluminum silicate and tannic acid are present by weight in a ratio in the range of 0.1:1 to 100:1.
9. (Previously Presented) The composition of claim 1 wherein the tannic acid to the active pharmaceutical ingredients is present by weight in a ratio in the range of 2:1 to 10:1.
10. (Previously Presented) The composition of claim 1 wherein the thickening agent is magnesium aluminum silicate and is present in a range of 0.5% to 10.0% by weight.
11. (Previously Presented) The composition of claim 1 wherein the suspending agent is xanthan gum and is present in a range of 0.5% to 10.0% by weight.
12. (Previously Presented) The composition of claim 1 wherein the sweetening agents include sucrose present in a range of 5.0% to 50.0% by weight, and sucralose and magnasweet MM-100 are each present in a range of 0.01% to 3.0% by weight.
13. (Previously Presented) The composition of claim 1 wherein the flavoring agent is artificial grape and is present in a range of 0.01% to 2.0% by weight.
14. (Currently Amended) The composition of claim 1 wherein the second solvent for the first dispersion is water and is present in a range of 10.0% to 85.0% by weight.
15. (Currently Amended) The composition of claim 1 wherein the second solvent for the first dispersion is glycerin and is present in a range of 2.5% to 20.0% by weight.
16. (Previously Presented) The composition of claim 1 wherein the preservative is methylparaben and is present in a range of 0.01% to 1.0% by weight.

17. (Previously Presented) The composition of claim 1 wherein the pH adjusting agents are sodium benzoate, citric acid, and sodium citrate, each present in a range of 0.05% to 1.0% by weight.

18. (Previously Presented) The composition of claim 1 wherein the anti-caking agent is magnesium aluminum silicate and is present in the range of 0.5% to 10.0% by weight.

19. (Previously Presented) The composition of claim 1 wherein the pH of said liquid dosage form is in a range of 3.5 to 6.5.

20. (Currently Amended) The composition of claim 1 wherein the ~~amount of pharmaceutically active tannate salts are~~ pyrilamine tannate ~~present at is~~ 30 mg, phenylephrine tannate ~~present at is~~ 12.5 mg, and dextromethorphan tannate ~~present at is~~ 25 mg.

21. (Original) The composition of claim 19 wherein said liquid dosage form is a suspension.

22 - 30. (Cancelled)

31. (Currently Amended) A composition ~~comprising a plurality of active pharmaceutical ingredients~~ consisting essentially of the active pharmaceutical ingredients phenylephrine, pyrilamine, ~~and~~ dextromethorphan, and excipients, the composition formed from a method comprising:

(a) ~~forming a solution by~~ dissolving the salt or free base of said active pharmaceutical ingredients in a solvent to form a first solution;

(b) ~~forming a powder mixture by~~ mixing a dispersing agent, diluent and tannic acid to form a powder mixture;

(c) combining the first solution and the powder mixture, without isolation or purification, to form tannate salts of the active pharmaceutical ingredients in a granulate; and

(d) combining said granulate with one or more excipients selected from the group consisting of diluents, dry binding/matrix forming agents, binding solutions, coloring agents, sweetening agents, hardness-increasing agents, flavoring agents; and combining the tannate salts without isolation or purification with at least one tablet excipient to prepare a homogenous granulation including pharmaceutically active tannate salts, the homogeneous granulation being in an amount to include a plurality of dosage units, the homogeneous granulation being homogeneous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units.

(e) processing said granulate into solid dosage forms.

32. (Currently Amended) The composition of claim 31, wherein the salt or free base of the active pharmaceutical ingredients are ~~free bases or salts~~ selected ~~from~~ from the group consisting of maleate, citrate, chloride, hydrochloride, bromide, hydrobromide, acetate, sulfate, mesylate, palmitate, and stearate, ~~and combinations thereof.~~

33. (Previously Presented) The composition of claim 31 wherein the tannic acid is natural or synthetic.

34. (Currently Amended) The composition of claim 31 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds, ~~and combinations thereof.~~

35. (Currently Amended) The composition of claim 31 wherein the solvents ~~are~~ is selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol, ~~and combinations thereof.~~

36. (Currently Amended) The composition of claim 31 wherein the diluent is selected from the group consisting of lactose, microcrystalline cellulose, sucrose and mannitol, and ~~combinations thereof, and~~ wherein said diluent is present in a concentration of 1.0% to 75.0%.

37. (Currently Amended) The composition of claim 31 wherein the binder solution comprises material selected from the group consisting of corn starch, potato starch, polyvinylpyrrolidone and xanthan gum, and ~~combinations thereof, and~~ wherein said binder solution is present in a concentration of 0.1% to 20.0%.

38. (Currently Amended) The composition of claim 37 wherein the binder solution further comprises a solvent selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol.

39. (Cancelled)

40. (Currently Amended) The composition of claim 31 wherein the dry binding/matrix forming agents are selected from the group consisting of methylcellulose, hydroxypropyl methyl cellulose, ethylcellulose, hydroxypropyl cellulose, xanthan gum and polyvinyl pyrrolidone, and

~~combinations thereof~~, and wherein said dry/binding/matrix forming agents are each is present at a concentration of 0.1% to 20.0%.

41. (Currently Amended) The composition of claim 31 wherein the coloring agents are selected from the group consisting of blue, red, yellow, green, orange, and purple, ~~and combinations thereof~~, and wherein said coloring agents are each is present at a concentration of 0.01% to 2.0%.

42. (Currently Amended) The composition of claim 31 wherein the sweetening agents are selected from the group consisting of sucrose, saccharin sodium, xylitol, magnasweet MM-100, and sucralose, ~~and combinations thereof~~, and wherein said sweetening agents are each is present at a concentration of 0.01% to 40.0%.

43. (Currently Amended) The composition of claim 31 wherein the flavoring agents are selected from grape, cherry, orange, lime and strawberry, ~~and combinations thereof~~, and wherein said flavoring agents are each is present in a concentration of 0.01% to 3.0%.

44. (Previously Presented) The composition of claim 31 wherein the dispersing agent is magnesium aluminum silicate and is present in 0.05% to 15.0% by weight.

45. (Previously Presented) The composition of claim 31 wherein the tannic acid is present in the range of 0.05% to 30.0% by weight.

46. (Previously Presented) The composition of claim 44 wherein the ratio of magnesium aluminum silicate to tannic acid is present in the weight ratio of 0.1:1 to 100:1.

47. (Previously Presented) The composition of claim 31 wherein the tannic acid and the active pharmaceutical ingredients are present in the weight ratio of 2:1 to 10:1.

48. (Previously Presented) The composition of claim 31 wherein the tannate salts are pyrilamine tannate present at 30 mg, phenylephrine tannate present at 25 mg, and dextromethorphan tannate present at 25 mg.

49. – 52. (Cancelled)

53. (Currently Amended) A ~~homogeneous~~ composition ~~comprising a plurality of consisting of the~~ active pharmaceutical ingredients comprising phenylephrine, pyrilamine, and dextromethorphan

tannate salts, the homogeneous composition being in an amount including a plurality of dosage units, the homogeneous composition being homogeneous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units, the homogeneous and excipients, said composition being formed by a method comprising:

(a) dissolving the salt or free base of said active pharmaceutical ingredients consisting essentially of phenylephrine, pyrilamine, and dextromethorphan in a first solvent to form a solution, wherein said first solvent is selected from the group consisting of purified water, ethanol, diethyl ether, methylene chloride, acetone, and isopropanol;

(b) mixing a dispersing agent and tannic acid in a second solvent to form a dispersion, wherein said second solvent is selected from the group consisting of purified water and glycerin; and

(c) transferring at least a portion of the solution to the dispersion, to form tannate salts of the active pharmaceutical ingredients, without isolation or purification to form a second solution, wherein said transferring results in a composition consisting of pyrilamine tannate, phenylephrine tannate and dextromethorphan tannate with reduced variability in active pharmaceutical ingredient content and increased certainty that said active pharmaceutical ingredients are delivered within a therapeutic range; and

(d) combining excipients to said second solution, wherein said excipients are selected from the group consisting of preservatives, suspending agents, thickening agents, coloring agents, anti-caking agents, sweetening agents, flavoring agents, pH adjusting agents, diluents, dry binding/matrix forming agents, binding solutions, and hardness-increasing agents.

54. (New) The composition of claim 1, wherein said active pharmaceutical ingredients are dissolved in said first solution separately.

55. (New) The composition of claim 1, wherein said first solution can be added in part to said first dispersion to form said second solution.

56. (New) The composition of claim 1, wherein the salt or free base of pyrilamine is maleate, of phenylephrine is hydrochlorate, and of dextromethorphan is hydrochlorate.

57. (New) The composition of claim 1, wherein said active pharmaceutical ingredients are dissolved under conditions that will not cause decomposition of said active pharmaceutical

ingredients and wherein said first solvent is selected from the group consisting of purified water, ethanol, diethyl ether, methylene chloride, acetone, and isopropyl alcohol.

58. (New) The composition of claim 1, wherein said second solvent is selected from the group consisting of purified water and glycerin.

59. (New) The composition of claim 1, wherein said combining said second solution with said liquid pharmaceutical carrier results in a composition consisting of pyrilamine tannate, phenylephrine tannate and dextromethorphan tannate with reduced variability in active pharmaceutical ingredient content and increased certainty that said active pharmaceutical ingredients are delivered within a therapeutic range.

60. (New) A pharmaceutical composition for oral administration in the form of a liquid suspension consisting essentially of pyrilamine tannate, phenylephrine tannate, dextromethorphan tannate, and a liquid pharmaceutical carrier.

61. (New) The composition of claim 60, wherein said liquid pharmaceutical carrier is selected from the group consisting of excipients, thickening agents, suspending agents, coloring agents, sweetening agents, flavoring agents, preservatives, pH adjusting agents and anti-caking agents.

62. (New) A pharmaceutical composition for oral administration in the form of a chewable tablet consisting essentially of pyrilamine tannate, phenylephrine tannate, dextromethorphan tannate, and excipients.

63. (New) A pharmaceutical composition of claim 62, wherein said excipients are selected from the group consisting of diluents, dry binding/matrix-forming agents, binding solutions, coloring agents, sweetening agents, hardness-increasing agents, and flavoring agents.

64. (New) The composition of claim 62, wherein said tablet contains 30 mg pyrilamine tannate, 25 mg phenylephrine tannate, and 25 mg dextromethorphan tannate.